Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Continuous quality improvement programs for pharmacies
Document preparation date	6/9/2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

Chapter 124 (HB2220) of the 2011 General Assembly mandates that the Board of Pharmacy promulgate regulations to specify the elements of a continuous quality improvement program that provides "*a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors.*"

The intent of the regulatory action is to implement the provisions of the Act in order to comply with the goal of reducing errors in dispensing. Regulations must be in effect within 280 days of enactment, so it is the Board's intention to adopt emergency regulations at its meeting on September 22, 2011. Before enactment of those regulations, the Board is seeking public comment on the regulatory elements of a continuous quality improvement program as outlined by the Ad Hoc Committee on CQI Programs and summarized in the Substance section of this document.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
…
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

The specific authority to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

The specific requirement for regulations is found in a new section of Chapter 33:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The following sections of the regulations have been identified as having issues that may need to be addressed in the promulgation of amended regulations:

- Definition of "dispensing error" to mean
    1. a variation from the prescriber's prescription drug order, including, but not limited to:
        - Incorrect drug;
        - Incorrect drug strength;
        - Incorrect dosage form;
        - Incorrect patient; or
        - inadequate or incorrect packaging, labeling, or directions;
    2. a failure to identify and manage:
        - therapeutic duplication;
        - drug-disease contraindications, if known;
        - drug-drug interactions, if known;
        - incorrect drug dosage or duration of drug treatment;
        - drug-allergy interactions; or
        - a clinically significant delay in therapy;
    3. a delivery of a medication to the wrong patient or unit, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy; and
    4. a variation in bulk repackaging or filling of automated counting devices, including, but not limited to:
        - Incorrect drug;
        - Incorrect drug strength;
        - Incorrect dosage form; or
        - Inadequate or incorrect packaging or labeling;
- An immediate requirement to report a dispensing error to the pharmacist on-duty;
- A requirement to initiate documentation of the dispensing error as soon as possible, not to exceed 3 days from determining their occurrence;
- A requirement that the documentation shall include, at a minimum, a description of the event that is sufficient to permit categorization and analysis of the event;
- A requirement that the pharmacist-in-charge or designee shall review each reportable dispensing error, analyze data collected and documented, assess the cause and any factors contributing to the dispensing error, to include any recommendations for remedial changes;
- A requirement to notify patient and prescriber when a patient has self-administered or been administered an incorrect drug;
- Language required for protection from discovery;
- An allowance to rid of the documentation regarding a dispensing error after the quality assurance analysis has been performed;
- A requirement to maintain a record indicating dates when the quality assurance analyses were performed, names of participants, general description of dispensing error, and corrective actions taken, if any;
- A requirement that the patient safety organization must be credentialed by the Agency for Healthcare Research Quality; and

- A definition of the term "actively reports" means documenting a dispensing error as soon as possible, not to exceed 3 days from determining their occurrence and reporting all reportable dispensing errors to the patient safety organization weekly.

In the development of regulations, there will be a number of issues to consider such as the definition of a dispensing error and the applicability of the regulations in institutional settings.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

Continuous quality improvement programs are increasingly important in health care organizations as a means of identifying systems and processes that may lead to errors. The Board of Pharmacy has supported the institution of CQI programs for a number of years. With the passage of HB2220, the Board is now mandated to promulgate regulations for CQI programs within 280 days or by December 20, 2011.

A third enactment on HB2220 requires that the Board of Pharmacy "work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act." To that end, a committee representing various fields of pharmacy practice reviewed the legislation and other information on CQI programs and concluded the law requires the drafting of regulations for pharmacies to either implement a continuous quality improvement program or actively report to a patient safety organization. Discussion primarily focused on possible subject matter for inclusion in the regulations.

Based on the subject matter for regulations identified by the Committee, the Board determined that it was necessary to publish a Notice of Intended Regulatory Action to allow for public comment prior to the adoption of emergency regulations. The work of the Ad Hoc Committee and public comment on the NOIRA will be considered by staff and the Committee in preparation of draft emergency regulations to be presented to the full Board for consideration on September 22, 2011.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.